Substantial Equivalence: The Review Process for Regular Reports

RECEIVED AS OF 3/24/14

Application Submission

PHASE 1

STEP 1 | SE Application Received

STEP 2 | Acceptance Review

STEP 3 | Acknowledgment or Refuse To Accept Letter

PHASE 2

STEP 4 | Grandfathered Status Check (if applicable)

STEP 5 | Assignment of Scientific Reviewers

PHASE 3

STEP 6 | Scientific Advice/Information Letter or Preliminary Finding Letter

STEP 7 | Order Letter

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You Submit an Application

You decide that you want to commercially distribute a new tobacco product in the United States that you believe is substantially equivalent to a predicate tobacco product.

You then submit an application for Substantial Equivalence to FDA

At least 90 days before you want to commercially distribute the new tobacco product.

Electronically through the Electronic Submissions Gateway or in paper format to the FDA Center for Tobacco Products (CTP)—for electronic submissions, first follow the Instructions for Registration and Submission.

A predicate tobacco product is one that was commercially marketed (other than exclusively in a test market) as of February 15, 2007, or one previously found to be substantially equivalent by FDA and in compliance with the requirements of the Food, Drug & Cosmetic Act.

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PHASE 1 | Receiving, Acknowledging, Checking for Completeness

STEP 1

FDA receives an application for substantial equivalence.

When we receive an application for substantial equivalence, we:

Stamp the date on it

Give it a Submission Tracking Number and put it in an internal tracking system

Assign a Regulatory Health Project Manager (Project Manager) within CTP's Office of Science to review it

Applications which are received after business hours are stamped the next business day.

PHASE 1 | Receiving, Acknowledging, Checking for Completeness

STEP 2

The Project Manager reviews the application to be sure that it is complete and that it describes a product under CTP's jurisdiction.

In this situation	We do this
Application is under CTP's jurisdiction and contains statutorily mandated items	Send an acknowledgment letter 
Application is: 1. Not under CTP's jurisdiction or 2. Missing statutorily mandated items or 3. A combination of the aforementioned	Send a Refuse to Accept letter 

PHASE 1 | Receiving, Acknowledging, Checking for Completeness

STEP 3

The Project Manager prepares and sends an acknowledgment letter to the applicant.

The letter includes:

- Name of applicant
- Full product identification
- Date we received the application
- Our submission tracking number
- Contact information for the Project Manager
- A general note from the Office of Compliance and Enforcement that the applicant may be contacted about grandfathered status (if applicable)

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PHASE 2 | Grandfathered Determination (if Applicable) and Reviewer Assignment

TRIGGER ACTION | Completion of Phase 1 with an acknowledgment letter issued

STEP 4

CTP begins review to determine if the predicate product can be considered grandfathered (if applicable).

- The Project Manager in the Office of Science sends a formal request to the Office of Compliance and Enforcement to begin reviewing the predicate tobacco product to determine if it can be considered grandfathered (GF).
    - Determination of the predicate's GF status is done either through the substantial equivalence (SE) report itself or by reference to a stand-alone GF submission.
    - Stand-alone GF submissions are submitted and reviewed separately from SE reports. If an SE report relies upon a stand-alone GF submission, the SE report should include the GF number associated with the stand-alone GF submission.
    - A submission for GF determination under SE review requires the same information that is needed for a stand-alone GF submission.

- The Office of Compliance and Enforcement may ask the applicant for more information to determine grandfathered status.

A grandfathered tobacco product is a tobacco product that was commercially marketed (not exclusively in test markets) in the United States as of February 15, 2007.

If you have any questions regarding your applications, please contact your assigned regulatory health project manager.

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PHASE 2 | Grandfathered Determination (if Applicable) and Reviewer Assignment

STEP 5

Project Manager assigns appropriate scientific reviewers.

Reviewers may come from these disciplines

Steps 4 and 5 are concurrent.

Who is appropriate as a reviewer depends on the contents of the application and on the results of earlier reviews.

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PHASE 3 | Scientific Review and Issuance of Decision

TRIGGER ACTION | Completion of Phase 2

STEP 6

Reviewers determine if more information is needed.
If so, Project Manager sends appropriate letter:

Scientific Advice/Information Request

We ask for specific information that we need or that would be helpful in making a decision about substantial equivalence. (Applicants have 60 days to respond to this type of letter.)

Preliminary Finding

We give a preliminary finding that the application does not support a substantial equivalence order. We list the deficiencies in the application and inform the applicant that if the deficiencies are not corrected, we will likely issue a not substantially equivalent order.

If no additional information is needed from the applicant, CTP determines if the product is substantially equivalent or not substantially equivalent.

PHASE 3 | Scientific Review and Issuance of Decision

STEP 7

The Project Manager sends an Order Letter based on the results of the scientific review:

Substantially Equivalent Order

We tell the applicant that the product is substantially equivalent (SE) and the manufacturer is authorized to sell or distribute it in interstate commerce.

Not Substantially Equivalent Order

We tell the applicant that the product is not substantially equivalent (NSE) and the manufacturer is not authorized to sell or distribute it in interstate commerce.* In order for the product to be sold, the manufacturer would need to apply for and receive authorization through one of the marketing pathways.

Withdrawal Confirmation

Applicants may withdraw an application at any time. If they withdraw the application, the Project Manager sends a letter acknowledging that withdrawal. That ends the process, no matter what phase the application is in.

**Any currently marketed product that receives an NSE order may no longer be sold or distributed in interstate commerce.*

This resource is intended to provide a high-level overview of the major steps that occur during review of an SE application.

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